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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas J. Monahan
Intellectual Property Office
The Pennsylvania State University
113 Technology Center
University Park, PA 16802-7000

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/21/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,940

Applicant(s)

FONASH ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7, 9-12, 14-118 is/are pending in the application.
- 4a) Of the above claim(s) 22-65 and 71-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-7, 9-12, 14-21, and 66-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 71-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 22 July 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 7/22/02 in Paper No. 11 is acknowledged and entered. Claims 1-3, 6-7, 9-12, and 14-21 are amended. Claims 66-118 are added. Claims 4-5, 8, and 13 are canceled. Claims 22-65 and 71-118 have been withdrawn from further consideration a being drawn to a non-elected invention. Claims 1-3, 6-7, 9-12, 14-21 and 66-118 are pending.
2. In the remark section, applicant has indicated that Claims 4-5, 8, and 13 are still pending (see pg. 14, second paragraph) and Claims 8, and 13 are amended, but the amendment indicated that Claims 4-5, 8, and 13 are cancelled. Therefore, Claims 4-5, 8, and 13 are not being examined on the merits. Claims 1-3, 6-7, 9-12, and 14-118 are pending.

Election/Restrictions

3. This application contains claims 21-65 and 71-118 are drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Newly submitted claims 71-118 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
The pending claims (Claims 1-3, 6-7, 9-12, 14-21 and 66-118) are group as follows:
 1. Group A: Claims 1-3, 6-7, 9-12, 14-21 and Claims 66-70 (new claims).
 2. Group B: Claims 71-94 (new claims).
 3. Group C: Claims 95-118 (new claims).

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Inventions of Groups A, B and C are unrelated and independent inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different required components that have different modes of operation and functions.

The feature of a deposited continuous thin film and radiation-driven desorption-ionization mass spectroscopy of Group A is not required by the claims of Group B and C. The feature of a deposited columnar/void thin film and a detection means of radiation-driven desorption/ionization mass spectroscopy of Group B is not required by the claims of Group A and C. The feature of a deposited columnar thin film and a detection means of radiation-driven desorption/ionization mass spectroscopy of Group C is not required by the claims of Group A and B.

Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group C would involve a determination of the patentability of the combination of a composition comprised of a deposited columnar thin film and a detection means of radiation-driven desorption/ionization mass spectroscopy (independent of its use) while a patentability determination for Group A would involve a consideration of the patentability of the combination of a composition comprised of a deposited continuous thin film and a detection means of radiation-driven desorption/ionization mass spectroscopy (independent of its use). These considerations are very different in nature.

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Further in Group B contains detection means in Claims 71 that are directed to the following patentably distinct species of the claimed invention:

- i) Group 1: radiation-driven desorption/ionization mass spectroscopy.
- ii) Group 2: antigen-antibody recognition reaction techniques.
- iii) Group 3: calorimetric detection.
- iv) Group 4: atomic force microscopy.
- v) Group 5: spectrographic analysis.
- vi) Group 6: enzyme reaction detection.
- vii) Group 7: electrical detection.
- viii) Group 8: chemical detection.
- ix) Group 9: fluorescent detection.
- x) Group 10: optical detection.
- xi) Group 11: radioactivity detection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, part of Claim 71 and Claims 72-94 is generic.

Further in Group C contains detection means in Claims 95 that are directed to the following patentably distinct species of the claimed invention:

- i) Group 1: radiation-driven desorption/ionization mass spectroscopy.
- ii) Group 2: antigen-antibody recognition reaction techniques.
- iii) Group 3: calorimetric detection.
- iv) Group 4: atomic force microscopy.

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- v) Group 5: spectrographic analysis.
- vi) Group 6: enzyme reaction detection.
- vii) Group 7: electrical detection.
- viii) Group 8: chemical detection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, part of Claim 95 and Claims 96-118 is generic.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 71-118 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Oath/Declaration

5. Applicant's submission of the oath/declaration in Paper No. 12 that corrected the defect in which Mr. Joseph Cuiffi citizenship was omitted is acknowledged and entered.

Drawings

6. The corrected or substitute drawings were received on 7/22/02. These drawings are acceptable.

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7. The previous rejections under 35 USC 112, first paragraph, 35 USC 102(b) of Bogart (US Patent 5,552,272), 35 USC 103(a) of Bogart (US Patent 5,552,272) in view of Ebersole et al. (US Patent 5,658,732), and 35 USC 103(a) of Dale et al (*Analytical Chemistry*, 1996, 68(19):3321-3329) in view of Ebersole et al. (US Patent 5,658,732) for claims 1-21 have been withdrawn in view of applicant's amendments and arguments. Upon further consideration, the following new grounds of rejection are made as follows. Therefore, this Office action is a non-final rejection.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3, 6-7, 9-12, 14-21 and 66-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The amended claim 1 recites the step of analyzing the sample by radiation-driven desorption-ionization mass spectroscopy.

The specification discloses the detection means or detection device for the method of analyzing a sample includes light desorption mass spectroscopy, antigen-antibody reaction detection, fluorescent detection, optical detection, radioactivity detection, electrical detection, and chemical detection (pg. 10, lines 8-16) and specifically the detection method of laser desorption/ionization time of flight mass spectroscopy (pg. 39, lines 4-21).

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Nowhere in the specification is there a teaching for a detection method of a radiation-driven desorption-ionization mass spectroscopy. The specification does not disclose the term "radiation-driven desorption-ionization mass spectroscopy". What type of mass spectroscopy is radiation-driven desorption-ionization?

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

b) The amended claim 7 recites that the criteria for selecting the deposited continuous thin film is selected from groups that included electromagnetic energy reflection, electromagnetic energy absorption, sample wetting and drying, sample species adsorption, desorption, and ambient desorption.

The specification discloses the criteria for selecting a particular film is based on properties of the film such as laser-light reflection, optical absorption, species absorption, and ambient absorption (pg. 9, lines 21-22).

Nowhere in the specification is there a teaching for selecting the deposited continuous thin film base on criteria that included electromagnetic energy reflection, electromagnetic energy absorption, sample wetting and drying, sample species adsorption, desorption, and ambient desorption.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

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c) The amended claim 9 recites that the deposited continuous thin film is modify by oxidation, halidation, silicidation, etching, ion implantation, hydrogen implantation, nitridization, and combinations thereof.

The specification discloses that the deposition of the film can be modify by adjusting the variables of the deposition conditions such as oxidation, silicidation, etching, voltage, current, voltage between plasma and substrate, substrate temperature, plasma power, process pressure, electromagnetic field in the vicinity of the substrate, deposition gases and flow rates, chamber condition, and substrate surface (pg. 8, lines 30-34 to pg. 9, lines 1-3).

Nowhere in the specification is there a teaching for modifying the deposited continuous thin film by halidation, ion implantation, hydrogen implantation, nitridization, and combinations of these methods. These types of modification methods are distinct methods and would produce a different type of deposited film. The deposited film produced by these types of modification methods would not be the same as the deposited continuous thin film define on Table 1 and pg. 18, lines 14-22.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

d) The amended claim 18 recites that the sample is applied to the continuous thin film directly from or integrated with a chemical, physical, or electrical separation means, and combinations thereof.

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The specification discloses that the sample is applied to the film directly from a chemical separation means including liquid chromatography, gas chromatography, and deposited thin-film chromatography (pg. 10, lines 4-6).

Nowhere in the specification are there a teaching for applying the sample to the film by integration with a chemical, physical, or electrical separation means, and combinations thereof. Further the specification did not disclose that the sample is applied by a physical, or electrical separation means.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

e) The amended claim 19 recites that the type of chemical, physical, or electrical separation means is selected from groups that included size exclusion chromatography, affinity chromatography, gel electrophoresis, capillary or micro-capillary electrophoresis, blotting, and combinations thereof.

The specification discloses that the sample is applied to the film directly from a chemical separation means including liquid chromatography, gas chromatography, and deposited thin-film chromatography (pg. 10, lines 4-6).

Nowhere in the specification is there a teaching for the type of chemical, physical, or electrical separation means that included size exclusion chromatography, affinity chromatography, gel electrophoresis, capillary or micro-capillary electrophoresis, blotting, and combinations thereof.

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In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

f) The amended claim 20 recites the method step of applying the sample to the continuous thin film directly from or integrated with a deposited thin film chromatography separation means. The steps includes applying the sample to the deposited thin film chromatography separation means and allowing the analytes of the sample to migrate through or interact with the deposited thin film thereby separating component analytes in the sample. Thereafter applying the analytes of the sample to the continuous deposited thin film.

The specification discloses that the sample is applied to the film directly from a chemical separation means including liquid chromatography, gas chromatography, and deposited thin-film chromatography (pg. 10, lines 4-6). The specification discloses the method steps for separation of analytes in a sample using a chemical separation means comprising a deposited thin film. The method comprising the steps of applying the sample to the deposited thin film and passing the sample through the deposited thin film whereby the analytes of the sample migrate through the deposited thin film thereby separating each analyte in the sample by mobility of each analyte (pg. 10 lines 24-26 to pg. 11, lines 1-3).

Nowhere in the specification is there a teaching for applying the sample to the continuous thin film integrated with a deposited thin film chromatography separation means. The method steps for applying the sample to the continuous thin film by deposited thin film chromatography separation means are not disclosed in the specification. The method steps of claim 20 would correlates with analyzing the sample by separation of analytes.

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In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

g) The amended claim 6 recites the type of deposited thin film is semiconductors, insulators, organic materials, glasses, plastics, polymers, metals, or ceramics.

The specification discloses that type of deposited thin film is a silicon film (pg. 18 lines 15-19).

Nowhere in the specification is there a teaching that the type of deposited thin film is insulators, organic materials, glasses, plastics, polymers, metals, or ceramics.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

h) The new claim 66 recites that the type of substrate is silicon, semiconductors, insulators, organic materials, glasses, plastics, polymers, metals, or ceramics.

The specification discloses that type of substrate is glass, metal foil, plastics and silicon wafers (pg. 20 lines 5-6).

Nowhere in the specification is there a teaching that the type of substrate is insulators, organic materials, polymers, or ceramics.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

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10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-3, 6-7, 9-12, 14-21 and 66-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The phrase “radiation-driven desorption-ionization mass spectroscopy” of Claim 1 is vague and indefinite because it is unclear what is meant by a “radiation-driven desorption-ionization mass spectroscopy”.
- b) It is unclear what the method steps are for the analysis of a sample of Claim 7 since it is just claiming the method of making the deposited continuous thin film. Further the step of selecting was not previously recited in Claim 1.
- c) The term “componentents” of Claim 70 is vague and indefinite because it is unclear what is “componentents”.
- d) Claim 14, “-” should be changed to -- for clarity.
- e) The method step of applying the analytes of the sample to the continuous deposited thin film after the component of the analytes have been separated in the deposited thin film of Claim 20 is vague and indefinite. Why is the analytes being applied onto the continuous deposited thin film when it has been separated on the continuous deposited thin film?
- f) It is unclear if the sample in Claim 20 is being applied onto the continuous thin film or onto the deposited thin film chromatography separation means.

- g) It is unclear if the deposited thin film is the same as the substrate because the type of deposited thin film claimed in Claim 6 is the same as the type of substrate claimed in Claim 66.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 6-7, 10-12, 14-17 and 66, 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Köster (US Patent 5,605,798).

Köster teaches a mass spectrometric processes for detecting a particular nucleic acid sequence in a biological sample (col. 3, lines 51-53). The biological sample includes solid materials such as tissue or cell pellets (Col. 7, lines 19-29). The solid supports include flat surfaces or chips, metal surfaces, or plastic (col. 7, lines 54-64). The nucleic acid molecule, which has been isolated from the biological sample (col. 7, lines 30-34), is immobilized to a solid support and includes a spacer region (a deposited continuous thin film) between the immobilized nucleic acid molecule and solid support (col. 3, lines 60-67 to col. 4, lines 1-4; col. 7, lines 65-67 to col. 8, lines 1-9). The methods of analyzing the nucleic acid molecule from the biological sample by mass spectroscopy include functionalizing the solid support to form OH-group on the polymer surface (col. 12, lines 33-63). Immobilizing the capture nucleic acid sequence on to the support and hybridizing the nucleic acid molecule from the biological sample

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with the capture nucleic acid sequence. After the removal of nucleic acid molecule that has not been hybridized, the sample is aird-dried and mixed with matrix solution that contains ammonium citrate before been analyzed by MALDI-TOF mass spectrometry. Köster's mass spectrometric processes anticipate the claim invention.

14. Claims 1-3, 6-7, 9-12, 14, 17-21 and 66, 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Apffel et al. (US Patent 5,705,813).

Apffel teaches a miniaturized integrated liquid sample handling system for matrix-assisted laser-desorption/ionization time-of-flight mass spectroscopy (MALDI-TOF MS) and methods of using such a system (col. 1, lines 5-13). The sample handling system is integrated with the MALDI ionization surface (col. 1, lines 66-67 to col. 2, lines 1-5). The ionization surface is composed of an inert material such as metal, glass, silica, or synthetic polymer (col. 7, lines 1-7) or modified to actively capture an analyte such as a nitrocellulose-coated MALDI probe (col. 7, lines 7-9) (col. 6, lines 53-67). The analyte can be obtained from biological sample such as biological fluids, or cell or tissue extracts (col. 3, lines 4-19). The system includes a "separation region" where chromatographic separations are carried out (col. 4, lines 45-47). For chromatographic-type separations, the microchannel separation region is coated with chromatographic matrices such as various stationary phases for HPLC or various ligands for affinity chromatography (col. 5, lines 5-15). One method of use disclose for the system is in the enzymatic digestion of a protein sample (col. 10, lines 6-30; fig. 6). The system comprise of the thin film support, a MALDI ionization surface, and an interconnecting microchannel. A portion of the microchannel contains an immobilized enzyme. The sample is first introduced into the

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sample reservoir, moved electrophoretically to the immobilized enzyme zone and allowed to react. The reaction products are electrophoretically moved from the immobilized enzyme zone towards the MALDI ionization surface. After all of the fragments have reached the ionization surface, the surface can be isolated, matrix can be added, and the support dried and presented for MALDI-TOF MS analysis. The device and method of use of Apffel anticipate the claimed invention.

Claim Rejections - 35 USC § 103

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 9 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apffel et al. (US Patent 5,705,813) in view of Hancock et al. (US Patent 5,716,825).

The device and method of use of Apffel are applied for the reasons discussed above.

The device and method of use of Apffel differs from the claimed invention by failing to include the method of modifying the deposited continuous thin film.

Hancock teaches an integrated nucleic acid analysis system for MALDI-TOF MS in a thin film support and method of use (col. 3, lines 1-5; col. 10, lines 39-64). The thin film support comprises a non-conducting material that includes a microchannel and a MALDI ionization surface (col. 4, lines 34-55). The system is formed by technique well-known in the art such as micromachining, or chemical etching.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Apffel by including method of modifying the deposited continuous thin film as taught by Hancock because both Hancock and Apffel teach an integrated liquid sample handling system for matrix-assisted laser-desorption/ionization time-of-flight mass spectroscopy (Apffel: col. 1, lines 5-13; Hancock: col. 3, lines 1-5). Therefore, one would have had reasonable expectation of success of including the method of modifying the deposited continuous thin film into the method of Apffel because both Hancock and Apffel teach the methods of using the thin film support for analysis system for MALDI-TOF MS.

Response to Arguments

18. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
October 15, 2002



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600